

## CLAIMS

What is claimed is:

1. A nucleic acid molecule comprising an adeno-associated viral vector and a  
5 promoter which is operably linked to a sequence encoding bone morphogenetic protein.

2. The nucleic acid molecule of claim 1, wherein said promoter is a promoter  
of bone morphogenetic protein.

3. The nucleic acid molecule of claim 1, wherein said promoter is a CAG  
promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

10 4. A nucleic acid molecule comprising an adeno-associated viral vector and a  
promoter which is operably linked to: (a) a nucleotide sequence of SEQ ID NO:1; or (b)  
a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

5. The nucleic acid molecule of claim 4, wherein said promoter is a promoter  
of bone morphogenetic protein.

15 6. The nucleic acid molecule of claim 4, wherein said promoter is a CAG  
promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

7. A vector comprising the nucleic acid molecule of any one of claims 1, 2, 3,  
4, 5 or 6.

8. A host cell comprising the nucleic acid molecule of claim 7.

20 9. A pharmaceutical composition comprising the nucleic acid molecule of  
any one of claims 1, 2, 3, 4, 5 or 6; and a pharmaceutically acceptable carrier.

10. A method of treating a disease or disorder in a subject in need thereof, said  
method comprising administering to said subject a therapeutically effective amount of a  
nucleic acid molecule comprising an adeno-associated viral vector and a promoter which  
25 is operably linked to a sequence encoding bone morphogenetic protein.

11. The method of claim 10, wherein said promoter is a promoter of bone morphogenetic protein.

12. The method of claim 10, wherein said promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

5 13. A method of treating a disease or disorder in a subject in need thereof, said method comprising administering to said subject a therapeutically effective amount of a nucleic acid molecule comprising an adeno-associated viral vector and a promoter which is operably linked to: (a) a nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

10 14. The method of claim 13, wherein said promoter is a promoter of bone morphogenetic protein.

15. The method of claim 13, wherein said promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

15 16. The method of claim 13 wherein the nucleic acid molecule is administered to a muscle of said subject.

17. A pharmaceutical composition comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein; a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably  
20 linked to a nucleotide sequence encoding bone morphogenetic protein; and a pharmaceutically acceptable carrier.

18. The pharmaceutical composition of claim 17, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

25 19. The pharmaceutical composition of claim 17, wherein said first promoter and/or said second promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

20. A host cell comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein; and a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein.

21. The host cell of claim 20, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

22. The host cell of claim 20, wherein said first promoter and/or said second promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

23. A method of treating a disease or disorder in a subject in need thereof, said method comprising administering to said subject a therapeutically effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter, and a second nucleic acid molecule comprising an adenoviral vector and a second promoter, wherein the first and second promoters are each operably linked to either: (a) a nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

24. The method of claim 23, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

25. The method of claim 23, wherein said first promoter and/or said second promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

26. The method of claim 23 wherein said first and second nucleic acid molecules are administered to a muscle of said patient.

27. A pharmaceutical composition comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a nucleotide sequence encoding a polypeptide; a second nucleic acid molecule

comprising an adenoviral vector and a second promoter which is operably linked to a nucleotide sequence encoding the polypeptide; and a pharmaceutically acceptable carrier.

28. A host cell comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a first nucleotide  
5 sequence encoding a polypeptide; and a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a second nucleotide sequence encoding a polypeptide.

29. A method of treating a disease or disorder in a subject in need thereof, said method comprising administering to said subject a therapeutically effective amount of a  
10 first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a first nucleotide sequence encoding a polypeptide; and a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a second nucleotide sequence encoding a polypeptide.

15 30. The method of claim 29 wherein the amount of the first nucleic acid molecule is higher than the amount of the second nucleic acid molecule.